Overview of USEPA's Glyphosate Risk Assessment

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Background Information

- Glyphosate was first registered in the US in 1974 as a non-selective herbicide registered to control weeds in various agricultural and non-agricultural settings
- Several human health analyses have been completed, including the registration eligibility decision (RED) in 1993
- Currently, glyphosate is undergoing Registration Review, a program mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to review pesticides at least every 15 years

Background Information

- Initial docket opening in 2009 with publication of human health scoping document and preliminary work plan (PWP)
- EPA released Draft Risk Assessments for Glyphosate, December 18, 2017
  - https://www.epa.gov/pesticides/epa-releases-draft-risk-assessments-glyphosate
  - Public comment period closed
  - Response to public comments document undergoing development
  - No major changes to US use expected. Only minor label changes to mitigate some ecological concerns
- Next steps:
  - No changes to human health or ecological risk assessment anticipated
  - Anticipate the proposed registration review decision scheduled to be published in 2019

Summary of Glyphosate Toxicology Profile

- Negligible accumulation in tissues
- Rapid excretion from the body (primarily unchanged parent, complete by 24 hours after exposure)
- Oral exposure considered primary route of concern but absorption is low
- Inhalation
  - Exposure expected to be minimal given low vapor pressure.
  - Low inhalation hazard with no effects close to the limit concentration.
- Dermal
  - Low hazard with no effects up to the limit concentration.
  - Dermal penetration has been shown to be relatively low for human skin (<1%)

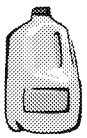
Exposure Profile in U.S.

- Anticipated routes of exposure evaluated by USEPA in 2017 risk assessment
  - Oral exposure considered primary route of concern due to low dermal penetration and low volatility
    - Exposure through food and water
  - Residential exposure when applying pesticide or entering treated areas, including children playing outside
  - Occupational workers handling pesticide prior to application (mixing/loading), during application, or when entering treated sites

Limit Dose: How much would 80 kg person need to ingest for 1,000 mg/kg/day?

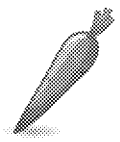
EPA

- Water = 0.159 ppm (high end estimate from direct aquatic application of glyphosate)



1,066,667 L/day

- Carrot = 0.5 ppm (legal limit but actual residues likely lower)



2,285,714 carrots/day

- Banana = 0.2 ppm (legal limit but actual residues likely lower)

3,389,831 bananas/day

USEPA, 2016/2017

- "***Not likely to be carcinogenic to humans***"
- *USEPA's analysis is more robust*
  - 61 epidemiology studies
  - 15 laboratory animal carcinogenicity studies
  - Only included genotoxicity studies internationally accepted for use in evaluation of human health effects
  - Considers exposure & hazard

International Agency for Research on Cancer (IARC), March 2015

- "***Probably carcinogenic to humans (Group 2A)***"
- *IARC's analysis is less robust*
  - 30 epidemiology studies
  - 8 laboratory animal carcinogenicity studies
  - Included studies in non-relevant species (e.g., worms, fish, oysters, alligators, plants)
  - Only considers hazard

USEPA, 2016/2017

- *USEPA's process is transparent:*
  - Convened an external peer review committee of scientific experts in cancer, genetic toxicology, statistics and risk assessment.
    - FIFRA Scientific Advisory Panel, December, 2016
  - Draft document provided in advance
  - Oral & written public comments
  - Public meeting that was also webcast
  - Transcript of the meeting (>1200 pages)
  - Final peer review report available March 2017
  - USEPA response to comment document published December 2017

International Agency for Research on Cancer (IARC), March 2015

- *IARC process lacks transparency*
  - Meetings are not accessible to the public
    - No public meetings are held.
    - Committee deliberations are closed.
    - Does not include public comments
  - There are no draft materials for evaluation in advance of the meeting.
  - Reports are published as final without any external peer review.
  - Conclusions not well described

Other Agency Decisions

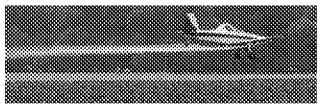
- Australia (2013) – weight and strength of evidence does not support the conclusion that glyphosate causes cancer
- Germany (2014) – no carcinogenic risk to humans can be concluded
- Canada (2015) – level of exposure to Canadians does not cause any harmful effects, including cancer
- European Food Safety Authority (EFSA) (2015) – Unlikely to pose a carcinogenic hazard to humans
- European Chemicals Agency (ECHA) (2017): Not classified as a carcinogen
- Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues (JMPR) (2016) – Unlikely to pose a carcinogenic risk to humans from exposure through diet
- New Zealand (2016)– Unlikely to be genotoxic or carcinogenic to humans

Important Variables Affecting Spray Drift

- *Droplet/Particle Size* is a primary factor affecting spray drift
  - Finer/smaller sprays are more drift prone, tend to behave like mists
  - Coarse or larger droplet size lead to less drift, tend to behave more like rain/showers and will follow a straighter path to the ground
- Weather Conditions: wind speed is the one of the primary factors that influences drift
  - Higher winds speeds carry droplets farther
  - Wind Direction: Changes in wind direction can lower total drift in a if application are being made downwind

Important Variables Affecting Spray Drift

- *Release Height and Application Methods*
  - Higher release/plane heights allows spray drift to travel farther, lower heights drift less
  - Use of fixed winged planes results in slightly more drift than rotary winged/helicopter



- Site characteristics:
  - Flat terrain in some ways can cause more drift especially if it has a low surface roughness (i.e., essentially the contour of the area that may be bare soil or field stubble) which impacts how much drift can be trapped as spray plumes move across such areas.

Factors Affect Droplet Size

- Physical properties of spray mixture
  - Spray Materials
  - Adjuvant/surfactant: solvent/oil based chemical adjuvants can be used to reduce drift
- Nozzle type and size: Nozzles that create larger sized droplets can reduce drift
- Higher spray/nozzle pressures used during the application creates a finer droplet size/mist and more drift potential
- Weather conditions: Weather conditions such as humidity and temperature can cause evaporation which can affect droplet size
- https://www.epa.gov/reducing-pesticide-drift

Glyphosate-specific Considerations

- In the case of glyphosate, a systemic herbicide is effective regardless of droplet sizes when it comes in contact with leaf/foliage surface area of the targeted crop (coca). *Therefore, increasing the droplet size will decrease drift.*
- In addition, use of on-board technologies can be applied to reduce drift. Some examples:
  - On-board computerized meteorological technology
  - Determination of wind effects on aerial application
  - Using GPS technology to accurately map aerial applications
- Current US registration application rates (8 lb ai/A, ~9 kg ai/hectare)are close to double that of the coca application rate (4.4 lb ai/A, ~5 kg a.i./hectare) for the GLY-41 formulation previously used
  - Based on US EPA methodologies, *exposure & risk to spray drift residues from the coca use would be lower than the US uses*
- USEPA has already assessed human health risk at the higher rates—*and concluded no risk to humans, including to children*

Example Drift Fractions at Various Distances Downwind From a Field Treated Using Aerial Equipment Using the AgDrift model

Droplet Size	Distance Downwind From Treated Field (feet)						
	0	10	50	75	150	200	300
Fine to Medium	0.257	0.209	0.129	0.098	0.054	0.041	0.028
Medium to Coarse	0.211	0.156	0.082	0.058	0.029	0.021	0.013
Coarse to Very Coarse	0.183	0.124	0.053	0.037	0.018	0.013	0.008
Fixed Wing Aircraft	0.234	0.183	0.105	0.078	0.042	0.032	0.021
Helicopter	0.218	0.171	0.086	0.063	0.034	0.026	0.018

Gracias
Thank You